

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

2:16 MD 1203

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 322 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 19, 2002, Dr. Evans attested in Part II of Ms. Primeaux's Green Form that she suffered from moderate mitral regurgitation and a reduced

3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$462,103.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Bryan Lucenta, M.D., noted, "There is mild to moderate mitral regurgitation present." Dr. Lucenta, however, did not specify a percentage as to claimant's level of mitral regurgitation.⁵ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the regurgitant jet area ("RJA") in any apical view is greater than 20% of the left atrial area ("LAA"). See Settlement Agreement § I.22.

In December, 2005, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared in October, 2002 by Dr. Evans based on her June 19, 2002 echocardiogram. In this report, Dr. Evans stated that "[t]here is moderate mitral regurgitation.... The RJA/LAA ratio is 25%."

echocardiogram demonstrated only mild mitral regurgitation. Dr. Oliner estimated claimant's RJA/LAA ratio to be 10%.

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Primeaux's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted an affidavit from Dr. Evans, wherein he stated that there was a reasonable medical basis for his Green Form representation that claimant had moderate mitral regurgitation because he "calculate[d] the RJA/LAA ratio to be 20%." Dr. Evans also stated that the echocardiogram was of adequate quality, was performed in accordance with the criteria outlined in the Green Form, and was interpretable. In addition, Dr. Evans noted that the moderate regurgitation he observed after examining multiple loops and still frames was not artifact, phantom jets, or backflow. Claimant argued that the affidavit of Dr. Evans provided a reasonable medical basis to support her claim. Ms. Primeaux further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Primeaux's claim.

basis' standard." (Emphasis in original.) Finally, claimant contends that she has satisfied her burden because the original auditing cardiologist who reviewed claimant's echocardiogram found a reasonable medical basis for the moderate mitral regurgitation finding of Dr. Evans.⁷

The Trust then issued a final post-audit determination, again denying Ms. Primeaux's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Primeaux's claim should be paid. On June 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6372 (June 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response and a supplemental response upon the Special Master. The Trust submitted a reply to claimant's response on September 6, 2006 and a reply to claimant's supplemental response on September 12,

7. In PTO No. 5632 (Aug. 26, 2005), we authorized the Trust to re-audit the claims of certain Diet Drug Recipients, including Ms. Primeaux, who opted out of the Seventh Amendment to the Settlement Agreement but did not elect to submit the initial audit of their claims to the Claims Integrity Process, based on the Trust's allegations that these initial audits were not reliable.

2006. Claimant submitted a sur-reply on November 1, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Ms. Primeaux has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

to pay the claim in accordance with the Settlement Agreement.
See id. Rule 38(b).

In support of her claim, Ms. Primeaux reasserts the arguments that she made in contest. Claimant also contends that the concept of inter-reader variability accounts for the differences between the opinion of the attesting physician and that of the auditing cardiologist. According to claimant there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Primeaux contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the supplemental opinion of Dr. Evans does not establish a reasonable medical basis for the claim because Dr. Evans does not rebut the specific findings of the auditing cardiologist, nor does he identify any high velocity sustained jets of mitral regurgitation seen in multiple consecutive frames that occupy at least 20% of the left atrium. The Trust also contends that the medical literature cited by claimant does not support Ms. Primeaux's argument that there is an "absolute" inter-reader variability of 15% in the quantification of mitral regurgitation, and that Dr. Oliner specifically determined that there was no reasonable medical basis for the finding of Dr. Evans. Finally, the Trust notes that the finding of the original auditing cardiologist is irrelevant to the proper disposition of this claims because (i)

Ms. Primeaux chose to have her claim re-audited pursuant to PTO No. 5632 and (ii) the basis for PTO No. 5632 was our determination that updated training for the Trust's auditing cardiologist's was warranted to protect the integrity of the Settlement Agreement.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson observed that:

In reviewing the transthoracic echocardiogram from 6/19/02, my visual estimate is that there is only mild mitral regurgitation. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in three representative cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $3.1 \text{ cm}^2/21.1 \text{ cm}^2$, $2.2 \text{ cm}^2/18.9 \text{ cm}^2$ and $2.5 \text{ cm}^2/19.7 \text{ cm}^2$. These ratios are 15%, 12%, and 13%, all of which are less than 20%, and are consistent with mild mitral regurgitation.

There was no mitral regurgitation tracing on the tape for me to critique. The mitral regurgitation jet is a small central jet.

In summary, it would be impossible for a reasonable echocardiographer to interpret the severity of this mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this patient has moderate mitral regurgitation, even taking into account inter-reader variability. Jane Primeaux has only mild mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not

adequately refute the findings of the auditing cardiologist or the Technical Advisor.⁹ She does not rebut Dr. Oliner's specific determination that the RJA/LAA ratio was 10%, nor does she rebut Dr. Abramson's conclusion that "all of [the RJA/LAA ratios] are less than 20%, and are consistent with mild mitral regurgitation."¹⁰ Neither claimant nor her attesting physician identified any particular errors by the auditing cardiologist or the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate mitral regurgitation cannot be medically reasonable where the auditing cardiologist estimated that claimant's

9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

10. For this reason, the reasons set forth in PTO No. 5632, and because claimant elected to have her claim re-audited, we also reject claimant's argument that the finding of the original auditing cardiologist provides a reasonable medical basis for the attesting physician's representation that Ms. Primeaux suffered from moderate mitral regurgitation.

echocardiogram demonstrated an RJA/LAA ratio of 10% and the Technical Advisor, based on her measurements, determined claimant's echocardiogram demonstrated RJA/LAA ratios of no greater than 15%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by $\pm 15\%$ would allow a claimant to recover benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.¹¹

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Primeaux's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

11. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in her statement, "There is no reasonable medical basis for the Attesting Physician's claim that [claimant] has moderate mitral regurgitation, even taking into account inter-reader variability."